EXHIBIT 5

PhRMA

June 7, 2004

VIA E-MAIL

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services

File Code: CMS-1380-IFC

Dear Administrator McClellan:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments in response to the interim final rule issued by the Centers for Medicare and Medicaid Services (CMS) on the submission of average sales price (ASP) data for certain Medicare Part B drugs and biologicals.[1] PhRMA is a voluntary, nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow Medicare beneficiaries to lead longer, healthier, and more productive lives. Investing an estimated $33.2 billion in the discovery and development of new medicines in 2003 alone, PhRMA companies are leading the way in the search for cures.

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the Act), payment for most drugs covered by Medicare Part B will be based on ASP beginning in 2005, and manufacturers must submit quarterly ASP reports for most Part B drugs beginning on April 30, 2004. Given the due date for the initial ASP submission, PhRMA and its members previously submitted materials to CMS to help identify the areas where manufacturers need clarification of the ASP reporting obligations.[2] PhRMA appreciates the efforts that CMS has made to

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[1] Medicare Program; Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals, interim final rule with comment period, 69 Fed. Reg. 17935 (April 6, 2004).

[2] See PhRMA Comments on Interim Final Rule on Medicare Program; Changes to Medicare Payment for Drugs and Physician Fee Schedule for Calendar Year 2004, 69 Fed. Reg. 1084 (January 7, 2004) (submitted March 8, 2004); see also PhRMA Questions and Comments for Consideration Concerning Manufacturer Submission of Average Sales Price Data for Medicare Part B Drugs and Biologicals (April 20, 2004).

provide guidance on ASP reporting, including the interim final rule, the April 20, 2004 Open Door Forum, and CMS's questions and Answers on the ASP reporting requirements.[3] Nonetheless, a number of unanswered questions and ambiguities remain, and CMS can achieve critical goals by clarifying and improving the interim final rule.

Most importantly, a final regulation that promotes accurate ASP calculations based on a methodology that avoids unnecessary volatility will reduce the risk that ASP-based payments cause disruption to providers and ultimately jeopardize Medicare beneficiaries' access to the medications they need. Even seemingly "technical" aspects of ASP calculations can have serious consequences for patients and providers. PhRMA has had a longstanding commitment to ensuring that patients have access to clinically appropriate medicines and remains dedicated to this goal. Moreover, we also believe that clear and specific regulations will aid CMS in its efforts to implement the Act's new payment system successfully. Accordingly, our comments are based on the following principles:

PhRMA Principles

1. **Patient access to care should be protected.** The new payment methodologies should maximize beneficiaries' access to innovative and clinically appropriate therapies in accessible settings.

2. **Providers' independent clinical decisions and choice of medicines must be preserved.** The new payment system should preserve the independence of providers' clinical decisions and minimize inappropriate payment barriers to choice of medicines. Moreover, CMS should not create financial incentives that encourage under- or over- utilization of services.

3. **Manufacturers should have adequate notice of reporting obligations and an opportunity to comment.** Manufacturers should be afforded meaningful notice, specific guidance, and the opportunity to comment on implementation of the Act's ASP reporting obligations.

4. **Manufacturers' reporting obligations should be clear, transparent, and explicit.** The reporting requirements for pharmaceutical manufacturers should be easily understood, feasible, practicable, and not overly burdensome.

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[3] "Average Sales Price Reporting Requirements, Questions and Answers" (the Q&A) www.cms.hhs.gov/providers/drugs/aspqa_web_042204.pdf (reviewed on May 17, 2004).

5. **Manufacturer-submitted sales, price, and commercial information should remain confidential.** Because of its proprietary and sensitive nature, CMS should recognize and maintain the confidentiality of information contained in ASP submissions.

Our comments are set forth in detail below.

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A. Notice to Manufacturers of Reporting Obligations and Their Termination

The interim final rule describes the drugs subject to ASP reporting as "certain drugs and biologicals covered under [Medicare Part B] that are paid under sections 1842(o)(1)(D)), 1847A, and 1881(b)(13)(A)(ii) of the [Social Security] Act."[4] However, both the rule and the Q&A fail to provide any additional specific guidance on how manufacturers can determine whether a drug is subject to the ASP reporting requirements. Whether a drug is covered by Medicare Part B is not always certain, and manufacturers cannot readily determine whether payment for a covered drug is based on specified sections of the Social Security Act. Manufacturers must have clear notice of: (1) whether a drug is covered by Medicare Part B (e.g., a list of covered drugs by NDC code); and (2) which categories of Part B drugs are not subject to ASP reporting. To help manufacturers obtain the information necessary to understand and fulfill their ASP reporting obligations, CMS also should establish a specific process by which manufacturers can request formal determinations as to whether a particular drug is subject to ASP reporting. In addition, CMS should specifically list all of the categories of Part B drugs that are not subject to ASP reporting.[5]

CMS should also state explicitly in the regulation that ASP reporting is limited to 11-digit NDC codes covered by Medicare Part B. If, for example, a drug is available in an injectable form covered by Medicare and in another form, the manufacturer should not be required to report ASP for the NDC codes corresponding to the non-covered form of the drug. Finally, CMS should specify that a manufacturer's reporting obligations end for a product upon the manufacturer's notification to CMS that is has discontinued or divested the product.

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[4] 42 CFR § 414.800.

[5] The preamble to the interim final rule cites radiopharmaceuticals as one example of Part B drugs that are not subject to CMS's, but does not provide any further information on which categories of Part B drugs are not subject to the CMS's requirements.

B. Definition of "Manufacturer"

Under the Act, the term "manufacturer" has the same definition for ASP-reporting purposes that it has under the Medicaid rebate statute.[6] For Medicaid rebate purposes, CMS has stated that the manufacturer "shall also mean the entity holding legal title to or possession of the NDC number" for the drug.[7] CMS should state in the rule that this principle also applies for ASP-reporting purposes, subject to a limited exception in cases where a manufacturer divests a product. In this situation, CMS should permit the divesting manufacturer to notify CMS that the acquiring company will begin reporting ASP for the product (and become its new "manufacturer") at a specified point that may occur before the process for transferring the NDC has been completed. This would ensure that a manufacturer would not be required to report ASP data that it did not generate (i.e., data generated by the company that acquired the product) merely because of a lag in transferring the NDC.

C. Sales Excluded from ASP Calculations/Separate and Supplemental Medicaid Rebate Agreements

While ASP calculations must include non-exempt sales to "all purchasers" in the United States,[8] the definition of "manufacturer" includes parties (e.g., repackagers or relabelers) that purchase from the original manufacturer. CMS has stated that sales to these "manufacturers" generally are not included in Best Price or AMP.[9] CMS should clarify whether, or in what circumstances, sales to manufacturer-purchasers should be included in ASP calculations.[10]

ASP calculations include all non-exempt sales to purchasers "in the United States."[11] For Medicaid rebate purposes, CMS considers the United States to include the 50 States and the District of Columbia (i.e., U.S. commonwealths, territories or possessions are not included). The Q&A clarifies that CMS defines

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[6] Social Security Act (SSA) § 1847A(c)(6)(A) (incorporating the definition of "manufacturer" in SSA § 1927(k)(5)).

[7] National Rebate Agreement, § I(l). See also 60 Fed. Reg. 48442, 48447 (Sept. 19, 1995) (proposed Medicaid rebate regulations) (requiring that the "manufacturer" possess legal title to the NDC "is necessary to permit a practical means for identifying . . . which manufacturer is responsible for paying the rebate" and "prevents duplicative manufacturer responsibilities for the drug").

[8] SSA § 1847A(c); 42 CFR § 414.804(a)(1).

[9] See Medicaid rebate release No. 29 (1997) ("Sales to Other Manufacturers Who Repackage/Relabel Under the Purchaser's NDC" are not included in AMP or Best Price); Medicaid rebate release No. 47 (July 13, 2000) (because the definition of Best Price specifically includes prices to HMOs, prices to HMO repackagers/relabelers should be included in Best Price calculations).

[10] The ASP Q&A states that repackagers must report ASP, but does not explain whether the original manufacturer's ASP calculations should include sales to repackagers.

[11] SSA § 1847A(c); 42 CFR § 414.804(a)(1).

the "United States" in this same manner for ASP-reporting purposes. This principle helps to establish a common baseline for ASP and Medicaid rebate calculations, and should be specified in the ASP regulation.

Moreover, CMS should list the categories of sales that are exempt from ASP calculations in its regulation[12] and (where necessary to ensure clarity) provide definitions clarifying the scope of these categories. For example, CMS should incorporate the definition of State Pharmaceutical Assistance Programs contained in its Medicaid rebate guidance[13] in the ASP regulation.

CMS guidance also provides that sales to wholesalers "which can be identified with adequate documentation as being subsequently sold to the excluded sales categories" are not included in Best Price calculations.[14] CMS should describe in the ASP regulations the types of documentation "adequate" to identify a sale to a wholesaler as an exempt sale and confirm that adequate documentation includes chargeback and rebate documentation, as well as documentation showing delivery to the customer.

Finally, CMS should specify in the ASP regulation when separate or supplemental rebates paid to the States are excluded from ASP calculations. CMS has previously stated that rebates paid to States under separate or supplemental Medicaid rebate agreements are only excluded from Best Price calculations if the agreement is approved by CMS.[15] CMS should specify whether this principle applies to ASP calculations. In addition, CMS should publish a list of states whose separate and supplemental Medicaid rebate agreements have been approved by CMS.

D. Administrative Fees

Consistent with the Act, the interim final rule provides that in calculating ASP manufacturers must deduct: (1) volume discounts; (2) prompt pay discounts; (3) cash discounts; (4) free goods contingent on purchase requirements; and (5) chargebacks and rebates (other than Medicaid rebates.)[16] The preamble to the rule notes that the Act permits CMS to specify other price concessions that should be included in ASP calculations after 2004.[17] However, the Q&A states that "administrative fees" paid to buyers should be included in ASP calculations if they

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12 The interim final rule provides that manufacturers should exclude from ASP "sales that are exempt from the Medicaid best price calculation under sections 1927((c)(1)(C)(i) and 1927(c)(1)(C)(ii)(III) of the [Social Security] Act." 42 CFR § 414.804(a)(4).

13 Medicaid rebate release No. 59 (June 23, 2003).

14 Medicaid rebate release No. 29 (1997).

15 See, e.g., Medicaid rebate release No. 48 (Nov. 15, 2000); Medicaid rebate release No. 53 (Feb. 27, 2002).

16 42 CFR § 414.804(a)(2).

17 69 Fed. Reg. at 17936.

"ultimately affect the price actually realized by the manufacturer." CMS should clarify that only those price concessions specifically enumerated in the statute should be included in 2004 ASP calculations. The Act expressly limits the types of price concessions that must be included in 2004 ASP calculations, and states that "*for years after 2004,*" CMS may include "other price concessions . . . that would result in a reduction of the cost to the purchaser."[18] Thus, the Act does not authorize CMS to require that manufacturers include "administrative fees" in 2004 ASP calculations, and the Q&A should be revised to clarify this point.

CMS should also reconsider the Q&A guidance on administrative fees with respect to post-2004 ASP calculations. A careful and orderly process for adding new price concessions to the list specified in the statute is itself an important safeguard that will help to promote accuracy in ASP calculations. By announcing a new category in proposed regulations, CMS can obtain comments on whether (or in what circumstances) the arrangement in question actually represents a "price concession," along with comments on any ambiguities associated with the proposal, and then use this information to develop a final regulation that provides a clear definition of the new category crafted to exclude arrangements that are not price concessions.[19] A cautious approach in which the repercussions of adopting a new category of "price concession" are fully considered in advance can help reduce the risk of generating ASP-based reimbursement rates that could jeopardize patient access to needed therapies. Caution is particularly important at this juncture, since the ASP-based payment system has not yet gone into effect and CMS has not had the opportunity to evaluate its affect on patient access.

E. The 12-Month "Rolling Average" Methodology For Estimating Price Concessions

The interim final rule provides that "to the extent that data on volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates [other than Medicaid rebates] are available on a lagged basis, the manufacturer should add the data for the most recent 12-month period available and divide by 4" to derive an estimate for the quarterly reporting period.[20] CMS should modify this estimation procedure so as to avoid unnecessary volatility in ASPs. Deducting a 12-month average calculated

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[18] SSA § 1847A(c)(3) (emphasis added).

[19] Moreover, apart from the improved decision-making associated with notice-and-comment rulemaking, adopting any new categories of price concessions through the rulemaking process will ensure that manufacturers can rely on the regulations to tell them what price concessions must be included in ASP calculations. Currently, 42 CFR § 414.804(a)(2) specifically lists five categories of price concessions that must be deducted in calculating ASP; manufacturers should be able to rely on this regulation, without fearing that the regulation may be misleading and searching for extra categories of price concessions that might be referenced in sub-regulatory guidance. Dissonance between the ASP regulations and sub-regulatory guidance will promote confusion and frustrate CMS's goal of ensuring that manufacturers' ASP calculations are based on a uniformly understood and consistently applied set of rules.

[20] 42 CFR § 414.804(a)(3).

in dollars from the ASP-relevant sales[21] for the quarterly reporting period could increase quarterly swings in ASP due to factors such as fluctuations in sales volume. In fact, in a quarter with unusually low sales, a rolling average deduction calculated in this manner could actually exceed the ASP-relevant sales revenue for that quarter, thereby resulting in a negative ASP. Negative ASP could result in volatile reimbursement rates and adversely affect patient access. To illustrate this problem, we have included an example that provides a concrete example of how CMS's estimation procedure could produce a negative ASP. Likewise, CMS's estimation procedure would also cause ASPs to increase due to above-average sales volume, even when the manufacturer's prices remained constant.

To minimize extreme fluctuations in ASPs, CMS should adopt a methodology based on the average ratio between estimated price concessions and sales revenue. Under this approach, the manufacturer would calculate the ratio between total ASP-relevant estimated price concessions and total ASP-relevant sales revenue during the relevant 12-month period; multiply the ratio by the total ASP-relevant sales revenue for the reporting quarter; and then subtract the resulting figure from the total ASP-relevant sales revenue for the reporting quarter. For example, if the average ratio over the relevant 12-month period were 12%, the numerator in the ASP calculation would be 88% of the ASP-relevant sales revenue for the quarter; consequently, the ASP would not increase or decrease merely because the quarterly sales volume was above or below average. By dampening spikes, this approach would produce more stability in ASP-based reimbursement rates, minimize disruption to physicians, and ultimately reduce the risk of overly-volatile reimbursement rates that could adversely affect patient access to Part B drugs.

PhRMA urges CMS to adopt this smoothing procedure in its final regulations and to take measures to forestall the problems associated with the interim final rule's estimation procedure in the interim. The Act clearly permits manufacturers to use a rolling average methodology of their own choosing for 2004 ASP submissions.[22] CMS should therefore promptly emphasize that manufacturers are not required to use the rolling average methodology in the interim final rule for 2004 ASP submissions; quick action is necessary to ensure that manufacturers are aware of the option to adopt appropriate estimation procedures that reduce volatility in reimbursement rates.

CMS also should specify how to apply the rolling average methodology when a product is divested to another manufacturer. If, for example, a manufacturer that acquires the product estimates rebates, is it necessary to obtain data on the

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[21] "ASP-relevant" sales refer to non-exempt U.S. sales; likewise, ASP-relevant chargebacks or rebates refer to chargebacks or rebates associated with non-exempt U.S. sales.

[22] See SSA § 1847A(c)(5)(A) ("[f]or years after 2004, the Secretary may establish a uniform [rolling average] methodology . . . to estimate [rebates and chargebacks]") (emphasis added).

previous manufacturer's average rebates for the product until it accumulates 12 months of its own rebate data? In addressing the issue, CMS should note that the acquiring company will not necessarily have the same pricing or estimation practices as the previous manufacturer of the product.

CMS should also confirm that many details of the rolling average methodology are governed by a key principle articulated in the Q&A: "In the absence of specific guidance in the Social Security Act or Federal regulations, the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the intent of the Social Security Act, Federal regulations and its customary business practices." For example, the interim final rule requires manufacturers to use a rolling average methodology "to the extent that data on [the specified price concessions] are available on a lagged basis"[23] but does not specify when data are available "on a lagged basis," thereby requiring manufacturers to make reasonable assumptions about this issue. Similarly, CMS should confirm that a manufacturer may reasonably determine that information on some but not all of the enumerated price concessions are available on a lagged based (e.g., data on rebates and chargebacks may be available to a particular manufacturer on a lagged basis, but not data on prompt pay discounts), and that the price concessions estimated via the rolling average could vary depending on the particular product and the practices of the particular manufacturer. In addition, CMS should confirm that a manufacturer can elect to consider rebates and chargebacks (and/or other categories of price concessions) in combination in determining whether data are available on a lagged basis, and can use a combined rolling average to estimate these amounts. Likewise, CMS should confirm that a manufacturer can elect to use the rolling average as a consistent method of accounting for a category of price concession (either generally, or for specific NDCs). Given the complex systems programming issues associated with calculating ASP, this will avoid undue confusion and could help ensure that ASP calculations are not distorted by "double counting" price concessions.[24]

CMS should also clarify that manufacturers may adopt reasonable procedures designed to ensure that exempt sales are treated properly. Some price concessions captured in a 12-month rolling average will have resulted from exempt sales, and should therefore be deducted from the estimate in some

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[23] 42 CFR § 414.804(a)(3).

[24] If, for example, data on some portion of the rebates generated by sales during a quarter become available by the close of the quarter and the manufacturer deducts those rebates from its quarterly sales revenue, but also deducts a rolling average estimate that reflects the same rebates (plus rebates from past quarters that were deducted during the relevant quarter), it may overstate rebates and understate ASP. To avoid this problem, a manufacturer could reasonably decide to use the rolling average as the consistent method of capturing particular categories of price concessions (e.g., if rebates paid on ASP-relevant sales of a product during the reporting quarter and the past three quarters averaged 10% of ASP-relevant sales revenues, the manufacturer may simply deduct 10% from its pre-rebate ASP-relevant quarterly revenue, without applying a duplicative deduction for "unlagged" rebates paid during the reporting quarter).

fashion. In some instances, for example, exempt sales to Federal agencies, 340B covered entities or State pharmaceutical assistance programs may generate chargebacks or rebates that would appear in the rolling average figure. Thus, appropriate adjustments in the rolling average estimate may be necessary to exclude price concessions associated with exempt sales.

F. Zero or Negative ASPs

Even if a rolling average methodology does not itself cause negative ASPs, a zero or negative ASP may still occur due to circumstances such as back order situations. CMS recognizes in the Q&A that zero or negative ASPs may occur and directs manufacturers to report zero sales. However, the Q&A does not specifically instruct manufacturers to report negative ASP amounts. Medicaid rebate guidance provides that zero or negative AMPs should never be reported; if a zero or negative AMP occurs in a given quarter, the manufacturer must report the last calculated AMP with a value greater than zero.[25] To help prevent data anomalies from affecting ASP-based reimbursement rates and creating access problems, CMS should specify that this policy also applies to zero or negative ASPs. Alternatively, CMS could state in its regulation on ASP-based payments that it will use the last positive ASP or the WAC to set payment rates if a zero or negative ASP occurs in a quarter.

G. Returns

In the Q&A, CMS directs manufacturers to subtract the value of returns from the numerator of applicable sales and subtract the number of units returned from the denominator to calculate ASP. In the Medicaid rebate context, the inclusion of returns in the calculation of AMP created anomalous results. In some cases, for instance, anomalies may occur if outdated product is returned and credit (return value) issued against the product is less than the current wholesale price. PhRMA therefore requests CMS to reconsider its guidance on returns and provide that manufacturers are not required to include returns in ASP calculations.

H. Allocating Price Concessions to Specific NDCs

The preamble to the rule states that "for situations in which a manufacturer is unable to associate volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates, with a specific NDC, the manufacturer will allocate those [price concessions] to associated NDCs," and that "[t]his association will be based on the

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[25] Medicaid rebate release No. 38 (Nov. 20, 1998).

percentage of sales (in dollars) attributable to each particular NDC within the group of NDCs for which the manufacturer can associate discounts, rebates, free goods, and chargebacks."[26] CMS should incorporate this principle into the actual regulations and clarify its application. For example, CMS should specify whether the "percentage of sales" for the relevant NDCs is measured during the current reporting quarter or over a longer period (and whether this differs depending on whether the category of price concession in question is estimated via the 12-month rolling average methodology). CMS should also specify whether the percentages reflect overall sales of the relevant NDCs (over whatever period) or only those sales that involve the price concession in question. (For example, if a purchaser receives a free good for purchasing $X of one NDC and $X of another NDC, is the value of the free good allocated 50-50 or in accordance with the overall percentage of sales for the two NDCs.) In addition, CMS should specify whether the percentage "in dollars" refers to dollar values before or after other relevant price concessions have been deducted.

I. Definition of "Unit"

ASP is calculated on a per-unit basis. The Act defines a "unit" as "the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids."[27] But the interim final rule defines a "unit" as "the product represented by the 11-digit National Drug Code."[28] This definition has created some confusion, since it seems to differ from the Act and (as the Q&A indicates) also differs from the "unit" definition used for Medicaid rebate purposes. Consequently, CMS should provide an example to help manufacturers identify the correct "unit" to use in calculating ASP.

J. Other Calculation Issues

As noted earlier, CMS stated in the Q&A that manufacturers can use reasonable assumptions in calculating ASP in the absence of specific guidance in the regulations or the Act.[29] This is an important principle that should be expressly incorporated in the final ASP regulation. As discussed above, for example, a manufacturer's reasonable assumptions will determine many details concerning its

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26 69 Fed. Reg. at 17936.

27 SSA § 1847A(b)(2)(B).

28 42 CFR § 414.802.

29 CMS has adopted this same principle in the Medicaid rebate context. See National Rebate Agreement § II(i) ("[i]n the absence of specific guidance in [the Medicaid rebate statute], Federal regulations and the terms of this agreement, the manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of [the Medicaid rebate statute], Federal regulations and the terms of this agreement" and must maintain a written or electronic record outlining these assumptions).

rolling average methodology and the specific categories of price concession that it estimates via the rolling average. Similarly, a manufacturer must rely on its reasonable assumptions to "fill in the gaps" in the statute and regulations concerning other aspects of ASP calculations (e.g., to determine when a sale occurs for ASP purposes, and whether rebates are recognized when the obligation to pay a rebate arises or when the actual payment is made).

CMS should also identify the exact method to calculate ASPs for new products. The Q&A specifies that manufacturers should report WAC in cases where the ASP during first quarter sales is unavailable.[30] But this instruction fails to clarify exactly what information manufacturers should use for new product data. Accordingly, CMS should further define the process for calculating ASP for a new product during the first reporting period.

K. Information Included in ASP Submissions

The Q&A states that manufacturers must report WAC: (1) for single source drugs and biologicals, if the WAC is less than the ASP for a particular quarter; or (2) where the ASP is unavailable during the first quarter of sales. CMS should incorporate this guidance in regulation.

The Q&A also states that manufacturers are not currently required to submit separate information on nominally-priced sales in their ASP reports, but that CMS may require such information to be reported in the future. If CMS later requires reporting of information on sales at nominal prices, it should incorporate the requirement in regulation and limit this information to the aggregate value of nominally-priced sales during the reporting period.

At the April 20th Open Door Forum, CMS explained that the "number of units" column in the ASP reporting form (Addendum B of the interim final rule) refers to the number of units (i.e., products represented by the 11-digit NDC code) that the manufacturer sold in non-exempt U.S. sales during the reporting quarter. This should be specified in the regulation.

The interim final rule also requires specified officials (the manufacturer's CEO, CFO or an individual who has delegated authority to sign for and reports directly to the CEO or CFO) to certify to the accuracy and completeness of the ASP report.[31] Manufacturers take the obligation to submit accurate and complete ASP reports very seriously, and thus have repeatedly tried to obtain the guidance necessary to ensure that this occurs. CMS's issuance of the interim final rule, the Agency's

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[30] Where ASP data for a product is not sufficiently available for an initial quarter, CMS may base payment on WAC or pre-Act payment methodologies. SSA § 1847A(c)(4).

[31] 42 CFR § 414.804(a)(6) (specifying the manufacturer officials required to execute the certification); interim final rule Addendum B (certification form).

dialogue with manufacturers, and the development of final regulations that address the ambiguities and omissions in the interim rule are all critical steps in this process. Given the many uncertainties that currently exist about the drugs subject to ASP reporting, the correct procedures for calculating ASP, and the information to be provided in the quarterly submissions, the foundation for a certification that reported ASPs are calculated accurately and that all information in the submission is complete is not yet in place. Consequently, CMS should provide the guidance necessary to enable manufacturer officials to execute such a certification, and suspend the certification requirement until this occurs. Because ASP certifications are not required by the Act, there is no need for a premature certification procedure. It is inappropriate to require manufacturer officials to execute certifications when the ground rules for ASP reporting are still taking shape. Developing well-defined ground rules is the key to ensuring accurate and complete ASP submissions, and manufacturers are committed to working with CMS on this essential task.

L. Procedural Issues

The interim final rule does not specify what procedures manufacturers should use to revise or correct ASPs. CMS should clarify whether manufacturers should use the same mechanism used for revising Medicaid rebate calculations, or specify another mechanism that should be used for ASP revisions. To minimize the possibility of any significant revisions in ASP (which could be more difficult to address than Medicaid rebate adjustments, since ASP revisions could affect quarterly reimbursement rates that CMS had already established), a rolling average methodology that dampens volatility in ASPs is essential. While such a methodology is important for a number of reasons discussed earlier, it will also minimize the potential for significant revisions in ASPs and the difficulties that CMS might encounter as a result of such revisions.

CMS should also establish "front-end" safeguards to correct inaccurate payment rates before they go into effect. At a minimum, CMS should run system edits (such as those performed on manufacturers' Medicaid rebate data) to identify potentially incorrect data as it is being processed at CMS, and then request the manufacturer to verify or correct the information before it is used to set payment rates. As suggested by Dr. Richard Lawlor, CMS could also establish a secure website to allow manufacturers to inspect and comment on proposed payment rates for individual HCPCS codes prior to their general release. CMS has established a similar procedure concerning hospital quality data, which gives hospitals a "preview period" to check the data before publication and alert CMS to errors.[32] Adopting such a preview process for ASP-based payment data would

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[32] See "Reporting Hospital Quality Data for Annual Payment Update, Frequently Asked Questions," p. 5.

enable manufacturers to bring potential errors to the attention of CMS before the quarterly rates are finalized, thus reducing the risk of inaccuracies that could cause disruptions for providers and adverse effects on patient access.

PhRMA also requests CMS to explain the process it will use to translate ASPs reported at the 11-digit NDC code level into ASP-based payment amounts and how it will use the "number of units" information in manufacturers' ASP-submissions. We recommend that CMS use a weighted average based on the reported ASPs for 11-digit NDCs that share a common HCPCS code (and conversely, calculate separate payment rates for 11-digit NDCs falling within different HCPCS codes). In addition, CMS should specify in its regulation the lag between the quarter for which ASPs are reported and the quarter in which they will be used to set payment rates.

M. Confidentiality of Submitted Information

In the April 20th Open Door Forum, CMS stated that ASP information is confidential and will not be disclosed outside of CMS except under very limited circumstances permitted by the Act.[33] The Q&A further states that CMS will not disclose such information "in a form that discloses the identity of a specific manufacturer . . . or prices charged for drugs by such manufacturer . . . except as necessary . . . to carry out the provisions of 1847A or 1847B of the Act, and to permit the Inspector General of [HHS], the Comptroller General, and the Director of the Congressional Budget Office to review the information provided." Consistent with the Act's principles of confidentiality, PhRMA requests that CMS specifically acknowledge that manufacturers' reasonable assumptions will not be disclosed except as expressly authorized by law.

N. Procedures for Updating ASP Guidance As New Issues Emerge

Finally, PhRMA urges CMS to declare its intended method of communicating ASP guidance to manufacturers on an ongoing basis as new issues emerge, and for periodically incorporating this guidance into its regulations in a timely manner. To make this guidance most accessible, CMS should create a separate manual for ASP guidance; new guidance would thus be issued initially in transmittals announcing changes in the ASP manual, incorporated into a separate manual, and ultimately incorporated in the ASP regulations. This process would help to ensure that manufacturers could easily locate relevant guidance on ASP calculations, and perform their calculations accordingly. Where feasible, CMS should make its ASP guidance consistent with Medicaid rebate guidance so that manufacturers are operating under a uniform set of ground rules.

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[33] SSA § 1927(b)(3)(D).

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In closing, PhRMA hopes that these comments are useful. We look forward to working with CMS on implementation of the Act's ASP reporting provisions, and trust that the Agency will not hesitate to contact us with questions, comments, or requests for additional information.

Sincerely,

Richard I. Smith
Senior Vice President for
Policy, Research, and Strategic Planning

Bruce N. Kuhlik
Senior Vice President and General
Counsel

ROLLING AVERAGE EXAMPLE

ASSUMPTIONS:

1. All product sales are non-exempt U.S. sales.

2. Rebates and chargebacks are estimated using the 12-month rolling average methodology, and are the only price concessions.

3. The gross sales price is $1 per unit and remains constant.

4. Combined rebates and chargebacks are 15% of the gross sales price (15¢ per unit) and remain constant.

5. Calendar year 2003 is the 12-month period used in calculating the rolling average deduction for 1Q04. Total gross 2003 sales are $40 million for 40 million units, and total 2003 rebates plus chargebacks are $6 million.

6. Gross sales for 1Q04 are $1 million (1 million units sold at $1 gross sales price).

RESULTS:

1. The 1Q04 rolling average deduction, calculated by dividing the 2003 rebate/chargeback total by four, equals $1.5 million. The 1Q04 ASP is ($1 million - $1.5 million) divided by 1 million, or - 50¢.

2. The 1Q04 rolling average deduction, calculated by the ratio method, is $150,000 (15% of $1 million). The 1Q04 ASP is ($1 million - $150,000) divided by 1 million, or 85¢.

EXHIBIT 6

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BNA's

Health Care Daily

REPORT

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News

Medicare

Cancer Groups Ask for Clearer Guidance On Part B Drug Reporting Requirements

Two leading oncology groups have warned that inappropriately low reimbursement rates for cancer drugs could result if the Centers for Medicare & Medicaid Services does not offer clearer guidance to pharmaceutical manufacturers on new cost reporting requirements for Medicare Part B drugs.

The two--the Association of Community Cancer Centers and the American Society of Clinical Oncology--expressed concerns that the manufacturers, fearful of enforcement actions or lacking clear guidance, might err on the side of caution and report artificially low prices to the federal government. Because Medicare payments for Part B drugs--those administered in physicians' offices--will be based on the data submitted by manufacturers, such actions could result in reimbursement rates to physicians that are lower than the prices at which physicians will be able to purchase the drugs.

The groups were commenting on an interim final rule that required the manufacturers to report pricing data for certain of these outpatient drugs as of April 30. The rule was published April 6, and the comment period closed on June 7 (No. 63 HCDR, 4/2/04). The rule implements provisions in the Medicare Prescription Drug, Improvement, and Modernization Act that require manufacturers to calculate the average sales price (ASP) of these drugs on a quarterly basis. To have a drug covered under Medicare, a manufacturer must submit not only the ASP, but the total number of units, wholesale acquisition cost and sales made at nominal price. Physicians will be reimbursed at ASP plus 6 percent for Part B drugs, beginning in 2005.

'Unnecessarily Low' Price Possible

John A. Keech, Jr., chairman of the American Society of Clinical Oncology's clinical practice committee, wrote that, because of inadequate guidance, manufacturers might report an "unnecessarily low" ASP to be conservative or because of a misunderstanding. "Adequate payment amounts for oncology drugs are essential for preservation of the cancer care delivery system," he said.

Writing on behalf of the Association of Community Cancer Centers, Patti A. Jamieson-Baker, the group's president, said in a June 7 comment letter that "[u]nder the new ASP payment methodology, accurate price reporting is essential to setting reimbursement rates that fully reflect the costs of providing cancer therapies." However, she said, "the interim final rule lacks the detailed guidance necessary to ensure that manufacturers will consistently and accurately report this information."

Manufacturers are subject to civil monetary penalties of up to $10,000 for each price misrepresentation.

ACCC, with a membership that includes hospitals and practitioners, asked CMS to implement an "exception process" by which interested parties could petition the agency to review external data for the purpose of setting a more accurate rate for the drugs.

Clarification is needed in other areas of the new ASP system, ACCC said. For each drug code, the ASP is calculated by dividing a manufacturer's sales by the number of units sold in that quarter. However, ACCC said that the the new law and the regulation define "unit" differently. "This difference could lead manufacturers to report data based on the wrong quantities, producing either significant errors in their data or dramatically increasing CMS's effort in calculating payment rates."

ACCC also said that CMS should establish a method for patients and providers to report difficulties in access caused by the new Medicare law, such as through a form on the Web site to collect questions and comments. The new Medicare Beneficiary Ombudsman program could be involved in monitoring patient care.

Making Data Available

CMS should make available immediately the projected 2005 payment rates based on the data manufacturers submitted on April 30, ASCO said. "CMS has indicated that it will publish those rates as part of the annual proposal on the physician fee schedule notice," the letter said. However, ASCO said that the schedule has been delayed in the past and that CMS should proceed as quickly as possible. The parties "would be best served by having as much time as possible to analyze the projected ASP-based payment rates and allow resolution."

In another area of the rule, ASCO said that although the ASP information is to be reported to CMS within 30 days after the end of each quarter, full information on rebates and chargebacks that purchasers earned may not be immediately available.

Because of this, the new law allows the manufacturer to apply a methodology based on a 12-month rolling average. However, the method described in the final rule "appears to require manufacturers to apply to the current quarter one-fourth of the dollar amount of the total rebates and chargebacks made in a previous 12-month period," ASCO said. "If the volume of drugs sold in the current quarter is less than in the earlier 12-month period, or if the rebates and chargeback practices have changed, this mechanical method could grossly exaggerate the rebates and chargebacks made in the current quarter, resulting in an artificially low ASP and therefore a Medicare payment rate that bears no resemblance to current prices."

ASCO suggested changes in the rebate calculations that it said would allow for a better gauge of the ASP in a particular quarter.

EXHIBIT 7

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris

NOTICE OF RULE 30(B)(6) DEPOSITION TO GSK

TO: ALL COUNSEL BY VERILAW

PLEASE TAKE NOTICE that, pursuant to Federal Rules of Civil Procedure 30(b)(6), the undersigned counsel will take the deposition of the representatives of the GSK Group who are knowledgeable regarding the matters set forth in Exhibit A attached hereto as well as matters set forth in Exhibit A to the Original Notice dated June 15, 2004. Such depositions will be recorded by stenographic and/or sound and visual means and will take place beginning at 10:00 a.m. Eastern Standard Time on June 15, 2004, at the offices of Hagens Berman LLP, One Main Street, Cambridge, Massachusetts 02142.

You are invited to attend and participate.

DATED: May 27, 2004

By **/s/ Steve W. Berman**

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EXHIBIT A

All of the definitions in plaintiffs' First Request for Production to Defendant Regarding HHS ASPs are incorporated by reference.

AREAS OF INQUIRY

1. The identity of drugs with respect to which ASPs were submitted to the federal government pursuant to the Interim Medicare Regulations.

2. The identity of ASPs for each such drug.

3. The AWP for each such drug.

EXHIBIT 8

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris

PLAINTIFFS' REQUEST FOR PRODUCTION TO DEFENDANTS REGARDING HHS ASPs

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure and LR D. Mass. 26.5 and 34.1, and pursuant to case management orders of this Court including the March 25, 2004 Order, the plaintiffs hereby request that each defendant produce the documents requested herein.

I. DEFINITIONS

1. Plaintiffs incorporate by reference herein all "Definitions", "Rules of Construction", "Instructions", "Drugs at Issue" "Relevant Time Period" from Plaintiffs Omnibus Requests For Production And Interrogatories To Defendants Abbott, Amgen, Aventis, Baxter, Bayer, Boehringer, Braun, Dey, Fujisawa, Novartis, Pfizer, Pharmacia, Sicor, TAP And Watson And To All Other Defendants With Respect To Drugs That Were Not Previously Subject To Discovery.

2. "Federal Health Care Regulators" means CMS, the United States Department of Health and Human Services, the Health and Human Services Office of the Inspector General, the General Accounting Office, Congress or any other federal institution, agency, department, or office concerned with pharmaceuticals.

3. "Interim Medicare Regulations" means Section 303, "Payment Reform for Covered Outpatient Drugs and Biologicals", of the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003,* Public Law 108-173, and the Interim Final Rules promulgated by CMS and reported in the Federal Register, including, but not limited to, actions released January 7, 2004 and April 6, 2004.

II. REQUESTS FOR PRODUCTION

1. All documents showing ASPs or ASP information you have provided for any AWPID pursuant to the Interim Medicare Regulations.

2. All documents, including internal memoranda and meeting notes, concerning the Interim Medicare Regulations.

3. All documents passing between you and Federal Health Care Regulators concerning the Interim Medicare Regulations.

DATED: May 26, 2004

By: /s/ Thomas M. Sobol

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